



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; comment request

The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on 15 August 2012 on page 48993 and allowed 60-days for public comment. 1 public comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

5 CFR 1320.5 (General requirements) Reporting and Recordkeeping Requirements: Final Rule

requires that the agency inform the potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. This information is required to be stated in the 30-day **Federal Register Notice**.

PROPOSED COLLECTION: *Title:* The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer. *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* This is to continue the Phase II follow-up of the Sister Study — a study of genetic and environmental risk factors for the development of breast cancer in a high-risk cohort of sisters of women who have had breast cancer. The etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have

been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible. Sisters of women with breast cancer are one group at increased risk for breast cancer; we would expect at least 2 times as many breast cancers to accrue in a cohort of sisters as would accrue in a cohort identified through random sampling or other means. In addition, a cohort of sisters should be enriched with regard to the prevalence of relevant genes and/or exposures, further enhancing the ability to detect gene-environment interactions. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. From August 2003 through July 2009, we enrolled a cohort of 50,884 women who had not had breast cancer. We estimated that after the cohort was fully enrolled, approximately 300 new cases of breast cancer will be diagnosed during each year of follow-up. Thus far 1,634 participants have reported being diagnosed with breast cancer. *Frequency of Response:* For the remainder of the study, women will be contacted once each year (when not scheduled for “triennial”) to update contact information and health status (10 minutes per response); and asked to complete short (75 minutes per response) follow-up interviews or questionnaires (“triennial”) every three years. Follow-up and validation of reported incident breast cancer and other health outcomes is conducted under Clinical Exemption CE 2009-09-004. *Affected Public:* Study participants, next-of-kin/proxies. *Type of Respondents:* Participants enrolled in high-risk cohort study of risk factors for breast cancer; next-of-kin/proxies. The annual reporting burden is as follows: *Estimated Number of Respondents:* 50,884 study participants or next-of-kin/proxies. *Estimated Number of Responses per Respondent:* See annualized table below:

Activity	Estimated Annualized Burden Hours			
	Estimated Number of Respondents	Estimated Responses per Respondent	Average Burden Hours per Response	Estimated Total Burden Hours Requested
Annual Updates	33,923	1	10/60	5,654
Follow-Up II (triennial)	16,961	1	1.25	21,202
TOTAL				26,856

*Average Burden Hours Per Response:*42 minutes; and *Estimated Total Annual Burden Hours Requested:* 26,856. The estimated total annualized cost to respondents \$537,120 (assuming \$20 hourly wage X 26,856). There are no capital, operating, or maintenance costs.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the project or to obtain a copy of the data collection plans and instruments, contact Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3-05, PO Box 12233, Research Triangle Park, NC 27709, or call non-toll free number (919)-541-4668 or E-mail your request, including your address to: sandler@niehs.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

October 25, 2012

(Date)

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